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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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08/591,447 04/18/96 QUENTIN-MILLET

M	XI/P-02956US0 EXAMINER
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ALEXANDRIA VA 22314

HM11/0217

ART UNIT PAK. M	PAPER NUMBER
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1646
DATE MAILED:

02/17/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 11-14-97 (Paper No. 17)
- ☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 54-78 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 54-78 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

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Art Unit: 1646

1. Applicant's election without traverse of Group I, claims 54-78, in Paper No. 17 is acknowledged.
2. The amendment filed 14 November 1997, Paper No. 17, has been entered.
3. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1646 (formerly 1812).
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. Applicant's arguments filed 14 November 1997, Paper No. 17, have been fully considered but they are not found persuasive.

Specification

6. The specification remains objected to because it does not comply with 37 C.F.R. 1.821 (d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification wherever a reference is made to that sequence. See M.P.E.P. 2422.04.

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As indicated in the last office action, the legends for figures 1-4 and 8-10 (on page 8) must identify each of the sequences disclosed in figures 1-4 and 8-10 with the individual SEQ ID NO:. Applicants argue that correct SEQ ID NO: in the legend will be submitted before formal drawings become due. Until such submission the objection will be maintained.

Claim Rejections - 35 USC § 112

7. Claims 54-78 remains rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a Tbp2 receptor of SEQ ID NO:2 and 4, does not reasonably provide the full scope of enablement for derivatives of Tbp2 receptor for the reasons set forth in last office action and discussed below. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants argue that the claims are directed only to fragments of Tbp2 and not to derivatives. However, as discussed in the last office action, claims 54-78 encompass Tbp2 derivatives and variants because of the recitation of an ~~derived~~.

8. Claims 54-78 remains rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described

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in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons set forth in the last office action and discussed below.

Applicants argue that deposit has been made and will submit an affidavit at a later time. However, until the indication that the strains are a publicly available deposit made under the terms of the Budapest Treaty as discussed in the last office action, the rejection will be maintained.

9. Claims 54-78 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 54-78 remains indefinite and confusing for the reasons set forth in the last office action and discussed below. SEQ ID NO:1 and 3 are DNA sequences and the claims are to polypeptide thus it is not clear how a maximal homology alignment can be performed using DNA sequences.

Claims 54-78 remains indefinite and confusing because of the recitation of ~~the~~ maximal homology alignment~~as~~ as discussed in the last office action. Applicants argue that the term 'maximal homology alignment' is clear on their face and are supported in the present specification. As discussed in the last office action, the metes and bounds of the term "homology" have not been

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clearly set forth neither in the claims nor in the specification. The precise meaning of "homology" in biology is having a common evolutionary origin" (Reeck et al.; R). The paper further explains that homology is a concept of quality or type of relationship between two or more things. Thus, amino acids or nucleotide sequences cannot exhibit a particular quantity or level of homology or percent homology. A more appropriate term is "identity." However, it should be noted that quantitative determination of identity requires subjective determinations for sequences compared. The state of the art is such that one skilled in the art cannot determine what is the meaning of the term "identity" without a precise algorithms with parameters i.e. "scoring rules and relationship analyzed"(George et al.(T), page 130, right column, top paragraph, is cited as of interest to the applicant). For example, consider hypothetical two sequences acgtac and acac. These can be compared in any of four ways.

acgtac	$4/6 = 67\%$	acgtac	$2/6 = 33\%$
ac--ac	$4/4 = 100\%$	acac	$2/4 = 50\%$

Thus, a specific definition of "identity" must be defined taking into considerations such variables as: complete vs partial sequence and gap distances.

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Claim Rejections - 35 USC § 102

10. Claims 54-77 remains rejected under 35 U.S.C. 102(b) as being anticipated by Legrain et al.(AS) for the reasons set forth in the last office action and discussed below.

Applicants argue that Legrain et al. disclose full length proteins or tryptic fragments whose sequence are not known whereas the claimed invention is directed to deleted fragments. However, the term "derived" is construed to encompass variants and derivatives and the claims encompass "derived" Tbp2 receptor. Furthermore, as discussed in the last office action, SEQ ID NO: 2 and 4 are identical to the TBP2 amino acid sequences of Legrain et al.(see attached sequence comparisons submitted in last office action).

11. Claims 54-76 and 78 remains rejected under 35 U.S.C. 102(b) as being anticipated by Quentin-Millet et al.(AM) for the reasons set forth in the last office action and discussed below.

Applicants argue that Quentin-Millet et al. Only indicates in very general terms that immunogenic fragments of Tbp2s may also be used instead of the full-length Tbp2 subunits, and does not disclose or suggest the Tbp2 fragments of the present invention. However, the term "derived" is construed to encompass variants and derivatives and the claims encompass "derived" Tbp2 receptor. Furthermore, the Tbp2 receptor inherently has the

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amino acid sequence of SEQ ID NO:2 and 4 because Tbp2 receptor of Quentin-Millet et al. is the same receptor isolated from the same strain.

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Pak whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stephen Walsh, can be reached on (703) 308-2957. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [stephen.walsh@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

msp
Michael D. Pak
1646
10 February 1998

Stephen Walsh
STEPHEN WALSH
SUPERVISORY PATENT EXAMINER
GROUP 1800